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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,247	11/05/1999	Thierry Sornasse	PA-0020 US	4960

27904 7590 02/26/2003

INCYTE GENOMICS, INC.
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER
SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/435,247	SORNASSE ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-9 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-9 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment B

Applicants' arguments, filed 02 December 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-9 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained and reiterated for reasons of record as stated in the previous action mailed: 21 May 2002. [This is a rejection based on a lack of Written Description.] Applicants argue that sequence identifiers along with Incyte clone identifiers were disclosed. This is found to be non-persuasive because although a sequence has been identified by a number, the exact sequence has not been disclosed.

Applicants further argue that the physical clone, i.e. the actual biological material on which the sequences are based are provided by Tables 1-4. However the exact sequences of the clones themselves are not disclosed since they are in the applicants holding and not deposited biological evidence. In addition, if the clones are available and at hand, the clones have an exact sequence that was not disclosed. Applicants state themselves that the noted sequences have unresolved bases due to sequencing errors. Thus until the sequencing errors are resolved, the exact sequence intended by the applicant remains uncertain. Applicant appears to admit that at

the time of filing, good sequencing and handling were not known thus resulting in erroneous bases within sequences (response):

> It would be a simple matter to determine the identity of those residues by sequencing the clones in Applicants' possession using standard sequencing methods. [...] In early publications of sequences, it was commonly known and accepted that the sequence might contain occasional sequencing errors and unidentified nucleotides, but the physical clone was useful despite any unresolved base(s).

At the time of filing the exact sequence of the clone as possibly intended by applicant was not disclosed, instead sequences containing unresolved bases from sequencing errors were provided. Although applicants are relying upon the clone, only the sequences with unsure/wildcard bases are disclosed thus leaving the sequence of the clone unresolved. Each variation, although they be known as "a, t, c, g, or other", provides a different nucleic acid sequence that can result in a different encoded peptide sequence and therefore carry out a different function.

Applicants also argue that "it has become standard practice for curators of databases to use N to mask those parts of sequences providing low information, such as repetitive elements, in order to optimize algorithmic searches for domains and motifs of far greater value" (p. 7, Amendment B). However the specification has not disclosed in anyway that the unresolved bases or N labeled bases were done so for the above listed reasons. The N's within the instant sequences do not carry the same purpose of application as applicants have pointed to, i.e. masking. Therefore, the arguments are non-persuasive to overcome the rejection.

Claims 1, 6 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant application fails to provide guidance to one of ordinary skill in the art for the method of screening a patient's sample for any immune response, disorder, condition, or disease as seen for example in claims 18-20 using the composition of claim 1. This rejection is maintained and reiterated for reasons of record as stated in the previous action mailed: 21 May 2002. [This is a rejection based on a lack of Enablement.] Applicants argue

Applicants point to page 17 line 11 to page 18 line 6, for a disclosure on how to use expression profiles to diagnose particular conditions, however first describe antibody labeling followed by a listing of various disease or disorders that are associated with altered expressions. No where does the indicated disclosure describe the make or use of expression profiles and the patterns that are generated by them. The same lack of disclosure is true for indicated page 18, lines 7-12 for which therapeutic treatment efficacy is stated to be taught; aside from the comparing of a patient sample to a standard sample for altered expression. The specification is speculative of possible recognizable patterns, which in turn, themselves may not reflect diagnostic capacities of significant medical conditions. Pattern analysis leads to profile generation, which in turn requires statistical analysis to determine meaning or sense from the data collected. Then, upon further experimentation possible thresholds must be met in order to determine any possible diagnostic, treatment therapy monitor, or medical condition analysis can be accomplished. In addition, applicants have only used two healthy individuals for generating standard measurements of expression analysis to a cocktail of cytokine treatments where as stated previously, demonstrates a significant degree of unpredictability in which cytokine induced the effects along with many other unpredictable events discussed in the previous office action. In addition, standard profiles need to be generated based on a representation of the population as a whole and not on only TWO individuals. It is unpredictable as to whether the standard profiles are required to be generated per ethnic population or geographic population, etc. Thus the standard pattern that will determine the basis of immune response analysis itself is unpredictable. Once the standard profile is generated, it is not disclosed what degree of resemblance is required in order to equate to a medical condition, or a specific medication condition at that. The further experimentation required, that is not merely quantitative, but unpredictable and without meaning until yet a further analysis of collected data is performed is undue experimentation. The further analysis may not lead to a predictable or recognizable pattern that will differentiate among various medical conditions. Therefore, the arguments are non-persuasive to overcome the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained and reiterated with respect to the term "specific" for reasons of record as stated in the previous action mailed: 21 May 2002. Applicants argue that the term "specific" in common usage denotes binding that exceeds background. This is not found to be persuasive due to some relative degree of specificity must be assigned if these profiles are to be generated; both standard and experimental in order for patterns within these generated profiles to be eligible for comparison. Therefore, the arguments are non-persuasive to overcome the rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 1 P.M to 8 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 24, 2003

Monika B. Sheinberg
Art Unit 1634

MBS

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600